Completing Records-Based Research Within the Military: A User's Guide

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Many of the orthopaedic studies completed within the military come from records-based research. This methodological article will assist researchers in completing such studies by highlighting the experiences and lessons learned from a recent retrospective study on amputees. Specifically, this article provides details on the various data sources available within the military, and how to access those systems, and offers general advice for the completion of retrospective studies using Department of Defense data systems. Although there are many obstacles that need to be overcome in order to successfully complete records-based research within the military, the authors hope this article will aid investigators in the completion of future projects. (Journal of Surgical Orthopaedic Advances 22(1):82–94, 2013)

Records-based research plays an important role in medicine (1, 2), especially in the improvement of care for combat-wounded service members. Although it is possible to follow a combat brigade (3) or patients with shoulder dislocations (4) prospectively, many questions, such as determining the effects that wound contamination has on wound infection, would be unethical to perform in a prospective manner. In situations such as these, where ethical or logistical restraints are prohibitive of prospective studies, retrospective research is critical.

The importance of military-based, retrospective studies can be seen by looking at recent studies examining the epidemiology (5–14), complication rates (15–22), and outcomes (23–27) of military personnel injuries. These studies have not only helped improve orthopaedic care for both service members and civilians alike, but also aided researchers and institutions in determining the feasibility of future studies (1, 28). Still, there remains a need for the improvement in the efficiency with which these retrospective projects can be completed (29).

Many of the larger, retrospective studies within the military involve service members from various bases who are treated at different institutions (5). Unfortunately, there is no centralized data source that contains the medical information necessary to appropriately address most combat- and noncombat-related research topics. Additionally, there are many barriers that are frequently encountered when trying to perform records-based research within the military. These include databases being maintained solely for medical treatment reasons, incomplete information within databases and registries, frequently changing points of contact for data systems, institutional review boards (IRBs) not having knowledge of what is contained within a data source or why access to the source is necessary for research purposes, the lack of central regulatory oversight committees for data that are not at the researcher's institution, and the inordinate time it takes to obtain access to each of the data sources essential to research projects. For many researchers, overcoming all of these hurdles is too time consuming, confusing, and daunting, thereby preventing them from completing their research project (1, 2, 30).

During the process of completing an analysis of all major extremity amputations incurred during Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND), the authors encountered many of these obstacles. Although records-based research methodology is project specific and difficult to generalize (31), this article uses the amputation study as a template to make recommendations for future records-based research projects. Although this article relates closest to combat-related injuries, the basic research principles and resources described can be extended to noncombat-related diseases and injuries as well. This review further aims to provide instructions as to which agencies need to be contacted, forms to be completed, and approvals are required to

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gain access to commonly used military data sources. The authors hope to reduce the difficulties encountered when performing military-based retrospective research within the Department of Defense by providing simplified, straightforward guidance.

Methods

Literature

A MEDLINE search was performed to identify articles that discussed records-based research using the following key words: chart review, retrospective research, records-based research, methodological studies, and research design. A review was then performed to identify previously published, retrospective studies within the military. These publications were used to identify the data sources that appeared to be the most commonly used within the Department of Defense for orthopaedic surgery research.

Characteristics of Combat-Related Amputations

Although there have been numerous studies examining major extremity amputations incurred during OIF, OEF and OND, there have been substantial methodological differences between them (3, 32–34). This lack of homogeneity has resulted in several knowledge gaps for war-related amputations despite the substantial impact these injuries have on the patients and medical system. The authors wanted to fill this gap by performing the largest single analysis of amputations to date. The first aim of this analysis was to identify the trends and characteristics of amputations that occurred during OIF, OEF, and OND over time (35).

Data Collection

After obtaining local IRB approval, data collection commenced. As Figure 1 shows, this data collection was a multistep process. The military amputation database, maintained by the Traumatic Extremity Injuries and Amputation Center of Excellence, was first queried to determine the names, amputation level(s), and demographic information for all of the major extremity amputees injured during OIF, OEF, and OND and an amputee case record file (CRF) (Fig. 2) was initiated for each amputee. These names were then provided to the Joint Trauma Theater Registry (JTTR) in order to gather injury-specific information for each patient. The JTTR was also able to provide epidemiologic statistics relating to the number of trauma admissions to the level IIB and level III facilities in Iraq and Afghanistan, along with deaths related to combat injuries. This information, along with demographic and deployment information on all service branches obtained from the Defense Manpower Data Center (DMDC), allowed for amputation trends to be analyzed.

The military amputation database, JTTR, and DMDC provided data in an organized format. These agencies took the investigators' request, found the information,
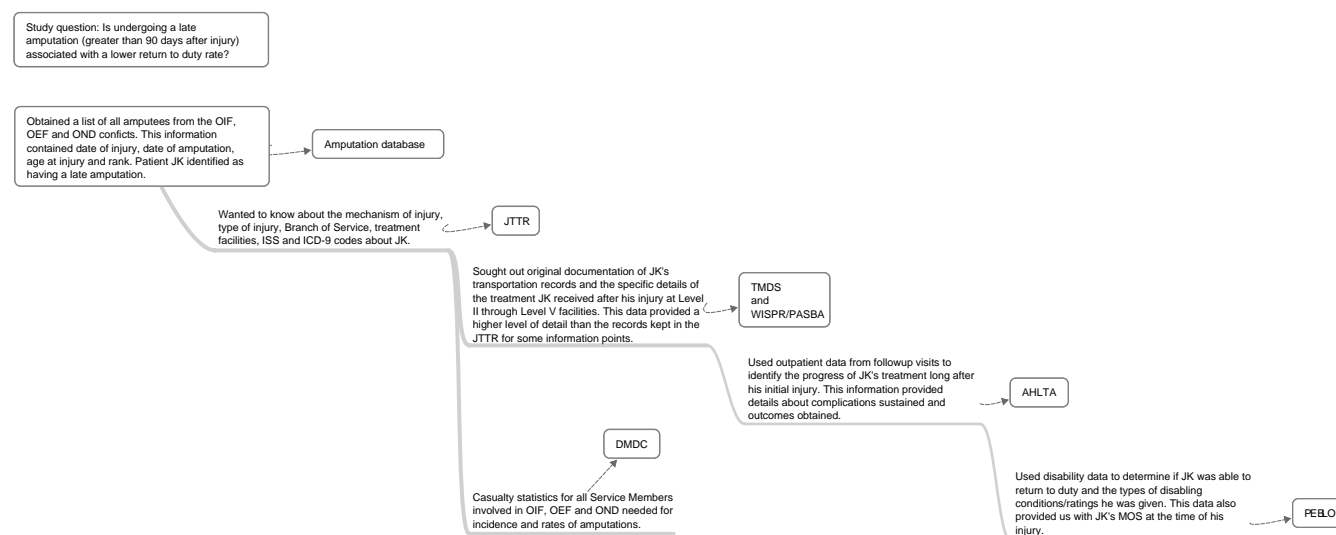

FIGURE 1 A flowchart for the data acquisition processes used for a retrospective study of amputees. OIF, Operation Enduring Freedom; OEF, Operation Enduring Freedom; OND, Operation New Dawn; ISS, Injury Severity Score; JTTR, Joint Trauma Theater Registry; DMDC, Defense Manpower Data Center; TMDS, Theater Medical Data Store; WISPR, Workforce Investment Streamlined Performance Reporting; PASBA, Patient Administration Systems and Biostatistics Activity; AHLTA, Armed Forces Health Longitudinal Technology Application; MOS, Military Occupation Specialty; PEBLO, Physical Evaluation Board Liaison Office.

Amputee CRF

Demographics

CRF ID: _____ ID: _____ Name: _____ SSN: ___ - ___ - ___ Gender: _____ Age: _____

Military Branch: _____ Rank: _____ MOS: _____ MOS Description: _____ Military OP: _____

Injury

Injury Date: ___ / ___ / ___ Injury Class: ☐ Battle ☐ Non-Battle | Mounted = 1; Dismounted = 2; Unsure = 3 |

MOI: _____ ☐ Penetrating ☐ Blunt Facility Level: _____ Facility Desc: _____

Location: ☐ Symes ☐ BK ☐ KD ☐ AK ☐ HD ☐ HP ☐ WD ☐ BE ☐ ED ☐ AE ☐ SD

Injury Narrative: _____

Amputation

First Amputation Date: ___ / ___ / ___ Weeks to Amputation: _____ Days to Amputation: _____ Amputation Category: _____

☐ Double ☐ Triple Quad

Patient at (please check one): ☐ WRAMC ☐ BAMC ☐ NNMC ☐ NMCSD ☐ WRNNMCB Status: _____

Inpatient Narrative: _____

ISS05 / AIS / PATCAT

ISS05: _____ AIS_1: _____ AIS_2: _____ AIS_3: _____ AIS_4: _____ AIS_5: _____ AIS_6: _____ PATCAT: _____

PDCAPS Case / PEB / Rating & VACodes / ICD codes

☐ PDCAPS Case PEB: _____ Date Received: ___ / ___ / ___ Result Date: ___ / ___ / ___

Final Result: _____ Combined Rating: _____

VACodes and Rating: _____

_____

_____

_____

ICD codes: _____

_____

_____

_____

FIGURE 2 An example of a CRF that could be used for the major extremity amputation project. Note: None of the information contained in the CRF is accurate. It is used for demonstration purposes only.

and provided the data to the researchers. Such was not the case for the Theater Medical Data Store (TMDS), Web Interface for Scanned Patient Records (WISPR), and Armed Forces Health Longitudinal Technology Application (AHLTA). These systems, once accessed, required the investigators to independently learn the systems and go through each amputee record independently. Because these sources were used to determine finer details about the injuries and treatments of the amputees, data collection from these systems was very time consuming.

The last data source used for the amputation study was the Physical Evaluation Board Liaison Office (PEBLO). This office compiles data on the physical outcomes of those service members who have been severely injured and recommended for a medical board. Each service branch maintains patient data for its service members and

no service branch has a formal contact to handle data requests from investigators.

JTTR, AHLTA, TMDS, and WISPR all required applications and approvals separate from, and in addition to, the original protocol. The length of time needed to gain access to these sources varied substantially. Some, such as the JTTR, required only a data request form and took only a matter of days to process. Others, such as TMDS and Patient Administration Systems and Biostatistics Activity (PASBA), required multiple documents to be processed at multiple offices and took over 5 months from application submission to approval.

Problems With Accessing the Necessary Data

There were many unforeseen problems encountered while trying to collect data for the amputation project. Although the length of time required for protocol and data access approval can be affected by many variables, the multilayered approval processes required for TMDS and WISPR substantially increased the time needed to complete the project. These delays were unforeseen and required exibility in regard to data collection and analysis. The investigators were fortunate to have data that could be analyzed from the amputation database and the JTTR while the TMDS and WISPR applications were being processed.

The reason so many different data sources were necessary for the amputation project is that the Department of Defense lacks a centralized data repository. This lack of a centralized data source increases the administrative duties for researchers and forces them to spend substantial time determining which agency, database, or repository contains the desired information. Decentralized data sources are especially problematic when patients have incomplete data in the multiple systems. Such a scenario is not uncommon within the military and it forces investigators to speculate whether data missing from one source either does not exist or if it is just present in a different data system. All of these factors increase the length of time necessary to collect the data and increase the likelihood of being unable to find the necessary information for which they are searching.

There is also no standardization of record keeping across the multiple data sources within the military and it is not uncommon for investigators to find con icting information (e.g., the date an injury occurred or the date surgery took place) between sources. This leads researchers to question the accuracy of the con icting data and makes it difficult to determine which data source should be used for the study. Adding to these inconsistencies is the fact that most data systems differ in design, accessibility, and data storage. These factors make it difficult to locate data, leading some investigators to apply for

access to multiple data locations in hopes that one of them will contain the desired data.

Most information obtained in records-based research is often at least two steps removed from the patient (31) and medical records often are not designed to be used for research purposes (Table 1). This increases the potential for bias (1) and variability within data (1, 36). Many of the data sources used in the military are compiled through the efforts of Department of Defense employees examining original charts and entering data into larger databases or registries. It is unknown what types of oversight are in place for these agencies, and many injured service members have electronic charts with well over 50 pages of scanned, barely legible writing.

Although data collection and processing errors may be mitigated by accessing original medical records directly (2), doing so may not be feasible for research projects that include large numbers of patients. In addition, obtaining data directly from patient charts has its own inherent limitations (30), and gaining access to original patient records, especially from theater, may require lengthy approval processes, such as those the amputation project investigators encountered for WISPR. Further complicating matters, it is currently not possible for a researcher at one medical treatment facility to gain access to another facility's inpatient electronic medical records system. This adds yet another logistical constraint to data collection

TABLE 1 Commonly used terms in records-based research and their corresponding definitions

Term	Definition
Database	A comprehensive collection of related data that is organized for convenient access to the specific data it contains. They are built specifically for certain data and designed to aid with the retrieval, review, and processing of data. Databases should be used to collect data prospectively. They are designed for research purposes and require IRB approval to be built and populated.
Data Repository	A real-time collection of data from a multitude of different clinical sources. Presents a generalized view of information specific to a specific patient or a large group of patients. These data are collected retrospectively and designed for performance improvement. An IRB-approved protocol is not needed to create a data repository but is needed if it is to be used to answer a research question.
Data Set	A collection of data, typically kept in a table.
Data Element	The specific unit of data that is entered into one row and/or one column of a data set.
Data Collection	The process by which data are taken from nonorganized formats and placed into an organized structure. Data collection is used to generate both data sets and databases but not data repositories.

and forces research teams to either add investigators at other institutions to complete the data collection or forgo the information contained within those records. Although adding researchers to a protocol is not difficult, adding collaborators to protocols in which there are multiple levels of approvals through the TRICARE Management Activities (TMA) and other agencies necessitates additional approval processes. The researchers for the amputation study wanted to look at the inpatient records for all of the amputees in order to gain valuable information regarding the treatment that each amputee was provided at the terminal medical center. However, it was decided that the administrative work and time needed to add investigators to the already approved study was not feasible given the project's timeline.

Data Processing

The collection of data for the amputation study was managed by one author but collected by multiple personnel. Having data collected by multiple individuals allowed each team member to focus on becoming familiar and consistent with one specific data source at a time. The lead author and a data management specialist then organized data using Microsoft Access (Microsoft, Redmond, WA) and Microsoft Excel (Microsoft, Redmond, WA). Although incorrect transfer of data from a case record file to an electronic database can add bias or error (36), such a transition of data was necessary for the organization and analysis of data from over 1200 research subjects.

Results

The authors were successful in their attempt to analyze the trends and characteristics of the amputees during OIF, OEF, and OND. The data collected included age at the time of injury, date of injury, date of first amputation, rank, amputation level, sex, military operation (OIF, OEF, or OND), dominant injury cause, dominant injury type, battle versus nonbattle injury, branch of service, Injury Severity Score, and Extremity Abbreviated Injury Score for each service member. Ratios such as the number of amputees per 100,000 deployed troops and the number of amputees per 100,000 traumatic admissions were also determined. These data, once organized and analyzed, were shared with an institutional statistician who assisted with graph, table, and figure production. Such visualizations provided the basis of the data section for the paper and allowed the authors to easily portray their data. Trends such as when the majority of amputations occurred, the correlation between service branch and multiple amputation likelihood, and the overall incidence of amputations

during the Iraqi and Afghanistan con icts were successfully displayed within the paper.

Discussion

Many important studies that have improved combat-casualty care and furthered orthopaedic science have been performed using records-based research. However, despite their prevalence and importance, these projects are a challenge to complete within a military population because of the difficulties involved with accessing patient data from the multiple data sources.

It became obvious during the completion of the amputation study that there was no clear guidance on how best to obtain the desired data. This caused the investigators to spend a substantial amount of time determining where the information they sought was located and how it could be accessed. To prevent future researchers from encountering these same problems, a table consisting of the most commonly referenced and used Department of Defense data sources is provided (Table 2).

Most of the resources listed in Table 2 are centrally owned, meaning that there is an approval process necessary for their use separate from, and in addition to, the processes imposed by the researcher's own IRB. This table would have been extremely valuable to us at the beginning of the amputation study to establish where information may be contained and how to access it. The authors recommend contacting these data systems when initiating a research project. This will allow the researchers to gain a better understanding of what information may be available within each source, while also starting a line of communication with the data system's staff that will undoubtedly be helpful as the project matures.

It is unlikely that the Department of Defense will ever have a fully centralized data source for all patient information; therefore, researchers must continue to access multiple data sources operated by different agencies for many records-based research projects. However, as opposed to trying to gain access to multiple data systems at once, it is recommend that novice investigators identify one source that they think will contain the majority of the desired information and focus on data collection from that source before seeking information from other data systems. This strategy will help investigators gain familiarity and comfort with one source, allowing for an improved understanding of how the system works and the data it contains. There is substantial data contained within many of these data systems, and gaining an in-depth understanding of one system for one project is likely to assist with the completion of future projects. The investigators who performed a large number of epidemiological

TABLE 2   Description of commonly used data sources for records-based research within the Department of Defense

Database	Owner	Data Elements Contained and Unique Aspects	How Obtain Access
Armed Forces Health Longitudinal Technology Application (AHLTA)	Local medical treatment facility or medical center	Contains outpatient medical records for specific patients treated at a local facility. Encounter notes from subspecialists, lab values, radiology reports, lab values, demographic information, soldier readiness, profile histories and medications. All information undergoes real-time updates.	Must perform local training for ALTHA system at your Medical Treatment Facility (MTF) or Medical Center (MEDCEN). Contact your local Information Management Division (IMD) for class times.

In order to use this system for research, it must be identified as a data source in the IRB protocol. If accessing records within an Investigator's local facility, local IRB/Privacy Board approval is sufficient.

If access records outside an Investigator's local facility, in addition to local IRB/Privacy Board approval, Second-Level Human Subjects Review and Privacy Review are required by the Office of the Under Secretary of Defense, Personnel and Readiness (OUSD P&R) and TRICARE Management Activity, respectively.

The OUSD P&R Second-Level Review Templates can be found in IRBNet on the OUSD P&R site. OUSD P&R only accepts application materials for Second-Level Review via IRBNet.

The TMA data sharing agreement application (DSAA) can be found at http://www.tricare.mil/tma/privacy/downloads/2011Sep16/DSAA.pdf http://www.tricare.mil/tma/.privacy/duas.aspx. |
| AHLTA Clinical Data Repository (CDR) | TRICARE Management Activities (TMA) | This centralized database houses all patient and clinical data from all MTFs worldwide. It exchanges clinical data between the CDR and the Veterans Affairs Health Data Repository. Contains information on TRICARE and HealthVet beneficiaries who are being cared for at the VA or a Department of Defense (DoD) treatment facility. It contains the same data points as the locally secured ALTHA systems. | Access must be specified within the IRB protocol. The data sharing agreement application (DSAA) can be found at http://www.tricare.mil/tma/privacy/downloads/2011Sep16/DSAA.pdf.

As part of the application, the investigator must provide a copy of the IRB-approved protocol and signatures from all investigators. http://www.tricare.mil/tma/privacy/duas.aspx

In order to request a data extraction from the MDR, a Level of Effort (LOE) must be developed by the AHLTA Sustainment Group within the Defense Health Information Management System (DHIMS) based on the data requested. Subsequent approval is by the Clinical Portfolio Management Board (CPMB) must be obtained before finalizing the DSA. |

TABLE 2   Continued

Database	Owner	Data Elements Contained and Unique Aspects	How Obtain Access
Clinical Data Mart (CDM) (from the MDR)	TMA	CDM is the clinical reporting tool for AHLTA, the military's electronic health record. CDM allows Military Health System analysts and clinicians to measure, analyze, and manage performance of patient care. CDM provides secure access to clinical patient data from AHLTA's CDR, the global storehouse of direct care health records. **This system was de-commissioned in June 2011.**	Access must be specified within the IRB protocol. The data sharing agreement (DSA) can be found at http://www.tricare.mil/tma/privacy/downloads/2011Sep16/DSAA.pdf. As part of the application, the investigator must provide a copy of the IRB-approved protocol and signatures from all investigators. http://www.tricare.mil/tma/privacy/duas.aspx
Composite Health Care System (CHCS)	Local MTF or MEDCEN	Used for patient registration so that an AHLTA record can be created. It only contains information for your local MTF. Contains inpatient records, laboratory results, radiology reports and medication histories. This system can be searched by your local IMD or patient administration data staff.	Must perform local training for CHCS system at your Medical Treatment Facility. Contact your local Information Management Division for class times. In order to use this system for research, it must be identified as a data source in the IRB protocol. If accessing records within Investigator's local facility, local IRB/Privacy Board approval is sufficient. If access to records is outside investigator's local facility, in addition to local IRB/Privacy Board approval, Second-Level Human Subjects Review and Privacy Review are required by the OUSD P&R and TMA, respectively. The OUSD P&R Second-Level Review Templates can be found in IRBNet on the OUSD P&R site. OUSD P&R only accepts application materials for Second-Level Review via IRBNet. The TMA DSA application can be found at http://www.tricare.mil/tma/privacy/downloads/2011Sep16/DSAA.pdf http://www.tricare.mil/tma/privacy/duas.aspx.
Defense Enrollment Eligibility Reporting System (DEERS)	Defense Manpower Data Center (DMDC)	Communicates with Military Health System Operational Systems Eligibility. Automatically downloads demographic and contact data of beneficiaries enrolled in TRICARE. Also contains information regarding the beneficiary's occupation and/or unit. Is updated to contain Medicare and MDR eligibility status as well.	Access must be specified within an approved IRB protocol. Information is protected under the Privacy Act and only individuals with the need to know will be granted access via an application completed by the military command and IMD.
Defense Manpower Data Center (DMDC)	Office of the Secretary of Defense	Collects personnel, manpower, financial, and injury information for the DoD. The Defense Casualty Analysis System contains data on the military personnel who had been injured or killed in conflicts involving the United States.	All updated information can be found at: https://www.dmdc.osd.mil/dcas/pages/main.xhtml. Information for specific time frames/data points can be found by e-mailing the DMDC at: DCAS.Helpdesk@osd.pentagon.mil.

TABLE 2 Continued

Database	Owner	Data Elements Contained and Unique Aspects	How Obtain Access
Defense Military Epidemiology Database (DMED)	Armed Forces Health Surveillance Center	Contains historical and current data on diseases and medical events for military personnel. This database allows investigators to gather information regarding disease/ injury rates and burden of disease for active duty populations.	Users must first register with DMED at: http://www.afhsc.mil/dmed/registra-tion.jsp. Users can then apply for DMED access at: http://www.afhsc.mil/dmed/. General information regarding DMED can be found at: http://www.afhsc.mil/aboutDmed Assistance can be found at: dmed.afhsc@amedd.army.mil.
Defense Medical Human Resources. System — Internet (DMHRSi)	TMA	DMHRSi integrates human resources data from a variety of sources allowing centralized access to manpower, personnel, labor cost assignment, education and training, and personnel readiness information for designated active duty, guard and reserve, federal civilians, contractors, and volunteers. DMHRSi provides personnel asset visibility to MHS leadership. It identifies who their personnel are, where they are working, where they are authorized, what positions are filled and what positions are vacant, projected gains or losses, what training their staff has received, the hours charged to each work center and to particular tasks, and roll-up reporting capabilities.	Access must be specified within the IRB protocol. Second-Level Human Subjects Review and Privacy Review are required by the OUSD P&R and TMA, respectively. The OUSD P&R Second-Level Review Templates can be found in IRBNet on the OUSD P&R site. OUSD P&R only accepts application materials for Second-Level Review via IRBNet. The TMA DSA application can be found at http://www.tricare.mil/tma/privacy/downloads/2011Sep16/DSAA.pdf. As part of the application, the investigator must provide a copy of the IRB-approved protocol and signatures from all investigators. http://www.tricare.mil/tma/privacy/duas.aspx
Expense Assignment System (EAS)	TMA	Expense Assignment System Version 4 (EAS IV) is a cost allocation tool delivering standardized reporting of workload, expense, and manpower data. EAS IV enhances health care resource management and supports decision making at all levels of the MHS.	The point of contact for this system is: csanto@plan-sys.com.
Essentris (Inpatient Electronic Medical Record)	Local MTF or MEDCEN	These records are the inpatient medical records kept at each medical treatment facility or medical center. They contain the hospital notes for all patients treated at those facilities. Each time the patient is admitted at a facility a new patient record is started.	Must perform local training for Essentris system at your MTF or MEDCEN. Contact your local IMD for class times. In order to use this system for research, it must be identified as a data source in the IRB protocol. As there is no MHS-wide access to inpatient records outside of the local facility, Investigators must identify collaborators at those outside facilities to access those records. IRB review at the nonlocal MTFs is required.

TABLE 2   Continued

Database	Owner	Data Elements Contained and Unique Aspects	How Obtain Access
Joint Theater Trauma Registry (JTTR)	Joint Trauma System (JTS)	JTTR is a data repository that collects and hosts all DoD trauma-related data. JTTR is used to document and provide timely information on care and outcomes of military and civilian trauma patients at follow-on medical facilities. Records contain, rank, branch of service, theater, mechanism of injury, type of injury, ICD9 and AIS injury codes, procedures, ISS scores, vital signs, fluids, TBSA burn information, lab values, complications.	The United States Army Institute of Surgical Research controls this resource. Typically, a meeting or a teleconference is scheduled to discuss the requests. Contact ISR_Data_Request@amedd.army.mil for information and the JTTR data request form.
M2 (Military Health System Mart)	TMA	MHS MART (M2) is a powerful ad hoc query tool used for summary and detailed views of population, clinical, and financial data from all MHS regions. With M2, analysts can perform trend analysis, conduct patient and provider profiling studies, and identify opportunities for transferring health care from the private sector to MTFs. It contains information on billing, RVUs, costs, and personnel.	Access must be specified within the IRB protocol. The data sharing agreement (DSA) can be found at http://www.tricare.mil/tma/privacy/downloads/2011Sep16/DSAA.pdf. As part of the application, the investigator must provide a copy of the IRB-approved protocol and signatures from all investigators. http://www.tricare.mil/tma/privacy/duas.aspx Requesting data extractions from M2: Local – MTF's DHCO will provide the data extraction if all data are from Investigator's local facility. MHS-wide– The Patient Administrations Systems and Biostatistics Activity (PASBA) office at Fort Sam Houston does all MHS-wide M2 extractions. www.dataanalysis-help@pasba2.amedd.us.army.mil.
Military Health System Data Repository (MDR)	TMA	MDR is the centralized data repository for the MHS providing executive information and decision support for secured electronic health care data from the enterprise down to individual recipients of care. MDR data resides on a secure computing environment where access is based on strict need-to-know mission essential requirements. The MDR captures and validates data from more than 260 DoD health data network systems worldwide and is the MHS's single point for data integration, data quality edits, online and near-line data storage, and DoD health care data transfers.	Access must be specified within the IRB protocol. The data sharing agreement (DSA) can be found at http://www.tricare.mil/tma/privacy/downloads/2011Sep16/DSAA.pdf. As part of the application, the investigator must provide a copy of the IRB-approved protocol and signatures from all investigators. http://www.tricare.mil/tma/privacy/duas.aspx Requesting data extractions from M2: Local – MTF's DHCO will provide the data extraction if all data are from Investigator's local facility. MHS-wide– The PASBA office at Fort Sam Houston does all MHS-wide M2 extractions. www.dataanalysis-help@pasba2.amedd.us.army.mil

TABLE 2   Continued

Database	Owner	Data Elements Contained and Unique Aspects	How Obtain Access
Pharmacy Data Transaction Service (PDTS)	TMA	The PDTS is a centralized data repository that allows us to build a common patient medication profile for all DoD beneficiaries regardless of the point of service they use. The PDTS was created to move the data from all MHS points of service — MTFs, TRICARE retail pharmacy networks, and the Mail Order Pharmacy contractor — to a single pharmacy claims manager that maintains a central repository. Establishing one central patient medication profile allows a provider to review a patient's complete medication history and therefore reduce his or her exposure to unnecessary safety risks that are present in a nonintegrated pharmacy system. It contains records for all DHP funded. It also contains information about prescribers, fillers, patients, drugs, and costs.	Access must be specified within the IRB protocol. Second-Level Human Subjects Review and Privacy Review are required by the OUSD P&R and TMA, respectively. The OUSD P&R Second-Level Review Templates can be found in IRBNet on the OUSD P&R site. OUSD P&R only accepts application materials for second level review via IRBNet. The DSA application can be found at http://www.tricare.mil/tma/privacy/downloads/2011Sep16/DSAA.pdf. As part of the application, the investigator must provide a copy of the IRB-approved protocol and signatures from all investigators. http://www.tricare.mil/tma/privacy/duas.aspx
Patient Encounter Processing and Reporting (PEPR)	TMA	PEPR is a suite of Web applications used to analyze purchased care claims data generated for the DoD MHS. PEPR assists in the analysis and reporting of billions of dollars in purchased care costs and workload data worldwide.	Access must be specified within the IRB protocol. Second-Level Human Subjects Review and Privacy Review are required by the OUSD P&R and TMA, respectively. The OUSD P&R Second-Level Review Templates can be found in IRBNet on the OUSD P&R site. OUSD P&R only accepts application materials for Second-Level Review via IRBNet. The DSA application can be found at http://www.tricare.mil/tma/privacy/downloads/2011Sep16/DSAA.pdf. As part of the application, the investigator must provide a copy of the IRB-approved protocol and signatures from all investigators. http://www.tricare.mil/tma/privacy/duas.aspx
Theater Medical Data Store (TMDS)	TMA	The TMDS data sources are AHLTA-Theater and THMP Composite Health Care System Cache (T2). It contains demographic information, pay grade, personnel code, unit ID, medical information from theater, discharge summaries from theater, and level V facilities for service members.	Access must be specified within the IRB protocol. Second-Level Human Subjects Review and Privacy Review are required by the OUSD P&R and TMA, respectively. The OUSD P&R Second-Level Review Templates can be found in IRBNet on the OUSD P&R site. OUSD P&R only accepts application materials for Second-Level Review via IRBNet.

TABLE 2 Continued

Database	Owner	Data Elements Contained and Unique Aspects	How Obtain Access
			The DSA application can be found at http://www.tricare.mil/tma/privacy/downloads/2011Sep16/DSAA.pdf. As part of the application, the investigator must provide a copy of the IRB-approved protocol and signatures from all investigators. http://www.tricare.mil/tma/privacy/duas.aspx Go to https://tmds.tmip.osd.mil/tmds/ to apply for system access. Contact ustchelp@ustranscom.mil.
Transportation Command (TRANSCOM) Regulating and Command & Control Evacuation System (TRAC2ES)	TRANSCOM	An application on MC4 laptops that helps deployed medical staff coordinate and monitor patient movement between medical treatment facilities during peacetime, contingencies, and war, including mass casualty situations. Interfaces with TMDS.	
Traumatic Extremity Injuries and Amputation Center of Excellence (EACE)	Department of Defense	Data contained on all amputees sustained during Operation Iraqi Freedom, Operation Enduring Freedom, and Operation New Dawn. Contains information on rank, amputation location, date of injury, date of amputation, and a brief injury narrative.	EACE is located in Fort Sam Houston, TX, and has a website that is under development at this time. There is no formal point of contact for this center and each research request is handled on a "case to case" basis.
Web Interface for Scanned Patient Records (WISPR)	Patient Administrations Systems and Biostatistics Activity	System developed by PASBA to capture and access inpatient records and scanned images of loose paper medical documentation from CENTCOM AOR. Inpatient and outpatient paper medical documentation from theater not generated via TMIP or AHLTA.	Must be specified in an approved IRB protocol to receive access to specific medical records. Contact WISPR@pasba2.amedd.army.mil for further information or for an WISPR IRB application template.

Note: Included within this table are descriptions for how to get access to these data sources.

studies using the Defense Military Epidemiology Database (10–14) and combat-related projects using information from the JTTR are great examples of how becoming familiar with one source can be extremely beneficial (16, 18, 37–39).

Focusing one's efforts on a single data source will also decrease the amount of time spent waiting for access to multiple data sources. The time needed to gain access can vary greatly between, and within, each data system because the process is quite unpredictable. However, if the investigator has worked closely with a resource in the past, it is likely that the process of gaining access will be faster than it would be otherwise. This was almost certainly a factor in the length of time it took the investigators of the amputation project to gain approval for TMDS and PASBA. Before that study, none of the investigators had worked closely with either agency and they were not familiar with the approval process. The novelty of these data sources led to some delays in paperwork being submitted and instances of both parties asking for additional information, slowing the approval process.

The authors also recommend developing a research team or network of collaborators when completing records-based research. Although an individual can certainly complete a research project on his or her own, having a team allows for each individual to concentrate on specific aspects of the study. Such networks can be formal [e.g., the Skeletal Trauma Research Consortium (40)] or informal, but the basic concept of sharing responsibilities in order to increase the efficiency of the team's work remains the same. In the case of the amputation study, one individual was particularly helpful in determining which applications and approvals were necessary to gain access to the desired data, while another was heavily relied on to provide an overarching perspective of the study. Without

these key team members, it is likely the research project would not have been completed.

Conclusion

Records-based research plays a vital role in both military and civilian medicine. However, this type of research is not without limitations and barriers, both of which are important to recognize before initiating research projects. The tables and recommendations included in this article should serve as a resource to help investigators determine where they need to look for specific information and how to best successfully complete their planned project. Although the amputation study used as an example is focused on combat-wounded service members, the principles contained within this article can easily be extended to noncombat-related orthopaedic conditions as well.

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